SENATE, No. 2364

STATE OF NEW JERSEY

212th LEGISLATURE

INTRODUCED DECEMBER 4, 2006

Sponsored by: Senator LEONARD LANCE District 23 (Warren and Hunterdon) Senator RICHARD J. CODEY

Co-Sponsored by:

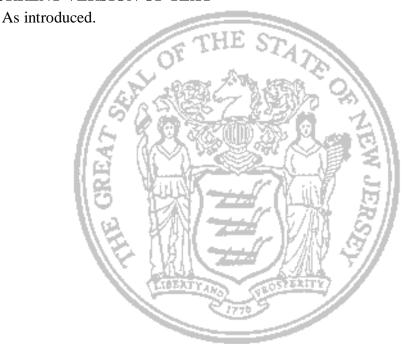
District 27 (Essex)

Senators T.Kean and Karcher

SYNOPSIS

Requires physicians and other prescribers to obtain informed consent from parents or guardians of minors for medications with "black box warnings."

CURRENT VERSION OF TEXT



(Sponsorship Updated As Of: 1/30/2007)

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AN ACT	concerning	the	prescribing	of	certain	medications	to
individ	luals under 1	8 yea	ars of age, an	id si	uppleme	nting Title 45	of
the Re	vised Statute	s.					

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

1. Prior to prescribing for an individual under 18 years of age any medication required by the federal Food and Drug Administration to have a "black box warning" on its labeling, a physician or other authorized prescriber shall inform the individual's parent or legal guardian about the possible side effects of the medication and shall obtain informed consent from the individual's parent or legal guardian for the notification.

A physician or other authorized prescriber who prescribes a medication in violation of this act shall be subject to disciplinary action by the State Board of Medical Examiners.

2. Prior to prescribing for an individual under 18 years of age any medication required by the federal Food and Drug Administration to have a "black box warning" on its labeling, an advanced practice nurse shall inform the individual's parent or legal guardian about the possible side effects of the medication and shall obtain informed consent from the individual's parent or legal guardian for the notification.

An advanced practice nurse who prescribes a medication in violation of this act shall be subject to disciplinary action by the New Jersey Board of Nursing.

3. The Division of Consumer Affairs in the Department of Law and Public Safety, in consultation with the Department of Health and Senior Services, shall adopt, pursuant to the "Administrative Procedure Act," P.L.1968 c.410 (C.52:14B-1 et seq.), rules and regulations necessary to implement the provisions of this act.

4. This act shall take effect 180 days after enactment.

STATEMENT

This bill requires physicians, advanced practice nurses, and other authorized prescribers to obtain informed consent from parents or legal guardians of minors prior to prescribing them medications that are accompanied by a "black box warning."

The United States Food and Drug Administration (FDA) requires pharmaceutical companies to place a "black box warning" on a drug label if medical studies indicate that the drug carries a significant

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- 1 risk of serious or life-threatening adverse effects. A "black box
- 2 warning" is the strongest warning that the FDA requires.
- 3 Pursuant to the bill, a physician, advanced practice nurse, or
- 4 other authorized prescriber in violation of the bill is to be subject to
- 5 disciplinary action by the applicable State professional licensing
- 6 board.